

Remarks

Claims 1, 4-26, 29-37 and 40-103 are pending; claims 53-103 are withdrawn from consideration as drawn to non-elected inventions; and claims 6, 31, 42 and 52 are withdrawn from consideration as being directed to non-elected species. With this response, claims 53-103 are canceled without prejudice to further prosecution in a continuing or divisional application; and claims 1, 26 and 37 are amended.

Claims 1, 4, 5, 7-12, 26, 29, 30, 32-37, 40, 41 and 43-51 stand rejected under 35 U.S.C. § 103(a). Reconsideration of the claims is requested, in view of the above amendments of the claims and the comments that follow.

Applicants note that the Power of Attorney filed August 12, 2002, has been accepted.

I. The Invention

The invention is directed to an oleaginous or oil-based pharmaceutical or cosmetic carrier containing, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent, wherein said solidifying agent is selected from the group consisting of at least one long chain fatty alcohol having at least 15 carbon atoms in its carbon backbone and at least one fatty acid having at least 18 carbon atoms in its carbon backbone. The proportions and composition of the solidifying agent and hydrophobic solvent are selected such that under ambient conditions the carrier is semi-solid at rest and liquefies upon application of shear forces thereto.

II. Amendment of the Claims

Independent claims 1, 26 and 37 have been amended to recite "an oleaginous

pharmaceutical or cosmetic carrier," by which it is meant of or pertaining to fats or oils or oil-based. It is submitted that the carrier, containing a fatty acid or fatty alcohol and a hydrophobic solvent, is oleaginous. No new matter has been added.

III. Rejection over U.S. Patent No. 6,224,888 to Vatter

Claims 1, 4, 5, 7-12, 26, 29-30, 32-37, 40-41 and 43-50 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Vatter. Applicants respectfully traverse the rejection.

The applicants maintains their position that the Vatter patent does not suggest the instantly claimed cosmetic or pharmaceutical carrier because the combinations of solidifying agents and emollients disclosed in the Vatter patent do not exhibit the instantly claimed carrier properties, namely, that the carrier is semi-solid at rest and liquefies upon application of shear stress thereto.

Vatter discloses the use of a solidifying agent to solidify a liquid base material (col. 8, l. 12-16). Solidifying agents are used in the preparation of "wax" or "gel" based formulations. A wax stick that is formulated as a lipstick or anti-perspirant does not become a liquid upon application of shear. Thus, the disclosed formulations do not meet this limitation of the claims. The Office Action suggests that the Vatter patent must inherently possess these properties because it discloses the materials and material proportions of the claimed invention. In fact, the Vatter patent discloses a wide range of ingredients, e.g., 0-90 wt% solidifying agent and 0-90 wt% emollient, and there is no teaching or suggestion of selection within the range of materials and combinations that will result in the claimed carrier properties.

Specific embodiments of the Vatter patent describe "wax stick" formulations containing about 10% to about 20% of a low melting wax, including fatty alcohols and fatty acids identified in the instant specification (e.g., col. 8, l. 31 et seq.); however, there is no teaching or suggestion of the use of 75-99 wt% hydrophobic solvent as a component of the carrier in these formulations.

Indeed, review of the patent examples directed to "wax stick" formulations, e.g., Examples 1-4, 6, 7, 14, establish that none of these formulations contain 75-99 wt% hydrophobic solvent. The only example of a wax stick formulation with greater than 75 wt% hydrophobic solvent (Example 12 contains 80 wt%) does not teach the use of the claimed fatty acid or fatty alcohols as solidifying agents.

The Examiner also pointed out during an interview on July 9, 2002 (summarized in an Interview Summary dated July 11, 2002), that Vatter contemplates gel or mousse formulations, which tend to liquefy under shear stress. See, col. 9, l. 23 et seq. While this is true, the gel formulations of Vatter do not employ a carrier having the claimed combination of 1-25 wt% fatty alcohol or fatty acid and 75-99 wt% hydrophobic solvent. Specifically, Vatter teaches:

Solidifying agents useful in the gel stick embodiments of the invention are, in general, surface-active compounds which form networks immobilizing or solidifying the liquid base materials into a gel. Such solidifying agents include: *soaps, such as the sodium and potassium salts of higher fatty acids, i.e., acids having from 12 to 22 carbon atoms*; higher acid (*sic*) fatty acid amides of alkylolamines; dibenzaldehyde-monsorbitol acetals; alkali metal and alkaline earth metal salts of the (*sic*) acetates, propionates and lactates; waxes, such as candelilla and carnauba waxes; and mixtures thereof (emphasis added).

Col. 9, l. 29-39. The Examiner has suggested that *soaps, such as the sodium and potassium salts of higher fatty acids, i.e., acids having from 12 to 22 carbon atoms* teach or suggest the claimed fatty acid solidifying agents. The salt of a fatty acid possesses

different propertied than its parent acid. Applicants respectfully submit that the salt of a fatty acid is not a teaching of a fatty acid. Nor would one of ordinary skill in the art be inclined to substitute one for the other, precisely because of their different properties in solution.

For the foregoing reason, applicants submit that Vatter does not teach or suggest the claimed invention; however, the applicants provide the following additional distinction over Vatter.

Vatter discloses a cosmetic composition containing vitamin B₃ as an active agent and a polar solvent, e.g., water, as an essential component. Vatter teaches that a polar solvent is used in significant amounts (“from about 0.1% to 80%, preferably from about 0.5% to about 60%, more preferably from about 1% to about 30% and most preferably from about 3% to about 18% polar solvent” (col. 5, l. 15-19). The emollients and solidifying agents of Vatter, the combination of which the Office Action considers suggest the instantly claimed invention, are only optional components in a water-based system. Thus, Vatter does not teach or suggest an oil-based carrier, as recited in each of the instant claims.

Vatter teaches the inclusion of vitamin B₃ as a cosmetic agent. There is no teaching of the use of the carrier of Vatter for pharmaceutical purposes. Thus, claims directed to pharmaceutical compositions and treatments of a disease using an active agent are not taught or suggested by Vatter.

For the foregoing reasons, it is submitted that the claimed invention is not anticipated or obvious in view of Vatter.

IV. Rejection over U.S. Patent No. 6,224,888 to Vatter in view of U.S. Patent No. 4,992,478 to Geria.

Claim 51 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Vatter in view of Geria. Applicants respectfully traverse the rejection.

Geria is relied upon to teach the use of anti-inflammatories in a topical composition. There is no teaching or suggestion of an oleaginous pharmaceutical or cosmetic carrier, comprising, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent, wherein said solidifying agent is selected from the group consisting of at least one long chain fatty alcohol having at least 15 carbon atoms in its carbon backbone and at least one fatty acid, having at least 18 carbon atoms in its carbon backbone. Therefore, Geria cannot address the deficiencies of the Vatter patent.

For the foregoing reasons, it is submitted that the claimed invention is not anticipated or obvious in view of Vatter in view of Geria.

V. Miscellaneous

A Petition for a three month extension of time accompanies this Response. A Request for Continuing Examination (RCE) also accompanies this Response. Please charge any additional fees due in connection with this matter, or credit any overpayment to Deposit Account No. 08-0219. If there are any questions, please call the undersigned at the telephone number indicated below.

Respectfully submitted,

Hollie L. Bahn, Reg. No. 31,321 / for

Mary Rose Scozzafava, Ph.D., Reg. No. 36,268
Attorney for Applicant

HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000
(617) 526-5000 (Facsimile)

APPENDIX

Amendments with Brackets and Underlining Showing Changes Made

1. (twice amended) [A] An oleaginous pharmaceutical or cosmetic carrier, comprising, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent, wherein said solidifying agent is selected from the group consisting of at least one long chain fatty alcohol having at least 15 carbon atoms in its carbon backbone and at least one fatty acid, having at least 18 carbon atoms in its carbon backbone and further wherein said solidifying agent includes a substance selected such that under ambient conditions, the carrier is semi-solid at rest and liquefies upon its application of shear forces thereto.

26. (twice amended) [A] An oleaginous pharmaceutical or cosmetic composition comprising, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent, wherein at least one of said solidifying agent and said hydrophobic solvent has a therapeutic or cosmetic beneficial effect, wherein said solidifying agent is selected from the group consisting of at least one long chain fatty acid, having at least 15 carbon atoms in its carbon backbone and at least one fatty acid, having at least 18 carbons in its carbon backbone and further wherein said solidifying agent includes a substance selected such that under ambient conditions, the carrier is semi-solid at rest and liquefies upon application of shear forces thereto.

37. (twice amended) A pharmaceutical or cosmetic composition comprising:

(a) [a] an oleaginous pharmaceutical or cosmetic carrier containing, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent; and

(b) a therapeutically or cosmetically effective amount of a biologically active substance; wherein said solidifying agent is selected from the group consisting of at least one long chain fatty acid, having at least 15 carbon atoms in its carbon backbone and at least one fatty acid, having at least 18 carbons in its carbon backbone and further wherein said solidifying agent includes a substance selected such that under ambient conditions, the carrier is semi-solid at rest and liquefies upon application of shear forces thereto.